

Attorney Docket No.: **WSTR-0014C**
Inventors: **Shiekhattar, Ramin**
Serial No.: **10/634,574**
Filing Date: **August 5, 2003**
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REMARKS

Claim 13 is pending in this application. Claim 13 has been rejected. Claim 13 has been amended. No new matter has been added by these amendments to the claims. Applicant is respectfully requesting reconsideration in light of these amendments to the claims and the following remarks.

I. Withdrawn Claim Objections/Rejections

Applicant acknowledges the withdrawal of the objection to claim 13, as well as the rejection of claim 13 under 35 U.S.C. 102(e) as being anticipated by Chiu (US 2007/0010434).

II. Rejection of Claims Under 35 U.S.C. 112

Claim 13 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. It is suggested that claim 13 refers to BRCC36 described in the specification at page 5 as SEQ ID NO:10, and it is unclear if "BRCC36" is narrow in scope or intended to include isoforms or homologous proteins from other species. Applicant respectfully disagrees with this rejection. In particular, it is respectfully submitted that one skilled in the art would readily appreciate, based upon the disclosure provided in the specification, the scope of the term "BRCC36." However, in the interest of facilitating the prosecution of this application, Applicant has amended claim 13 to indicate the BRCC36 protein of SEQ ID NO:10. Support for this amendment is found at page 5 of the specification. In light of this

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amendment, it is respectfully requested that this rejection be reconsidered and withdrawn.

III. Rejection of Claims Under 35 U.S.C. 103

Claim 13 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson ((1996) *Proc. Natl. Acad. Sci. USA* 93:4851-4856) or Atkins (U.S. Patent No. 5,932,435) in view of Fisch ((1993) *Oncogene* 8:3271-3276) and further in view of Driver ((1999) *Nat. Biotech.* 17:1184-1187). It is suggested that Robinson teaches assays for assessing candidate antisense molecules as inhibitions of expression of VEGF. It is further suggested that Atkins teaches assays in whole cells to assess by immunoprecipitation the effect of antisense molecules on the production of VEGF protein. The Examiner acknowledges that neither Robinson nor Atkins teaches an assay for testing antisense molecules for their effect on BRCC36 (c6.1A) protein production; however, Fisch is suggested to teach the protein and cDNA sequences of BRCC37 and the association of disruption of the BRCC36 gene in to cases of pro-lymphocytic leukemia. It is suggested that the prior art provides the necessary structure for designing candidate antisense molecules for inhibiting BRCC36 gene expression and further teaches assays for assessing such molecules. The Examiner further asserts that the prior art provides the motivation for combining the teachings of Robinson or Atkins with the teachings of Fisch for the purpose of testing candidate antisense molecules to find antisense or ribozyme molecules that effectively inhibit protein production, because Driver teaches that antisense molecules are useful in a

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technique for analysis of gene function in utero to uncover both primary and secondary phenotypes. It is suggested that in view of the teachings of Fisch that loss of c6.1A gene expression occurs in examples of T-cell prolymphocytic leukemia, it would have been *prima facie* obvious to one of ordinary skill in the art to have combined the methods of Robinson or Atkins with the teachings of Fisch, which provide the structure of BRCC37 (c6.1A) gene art to make the claimed. The Examiner concludes that the motivation to do so would have been to further study the effect of c6.1A gene expression loss to discover its affect, if any, on T-cell leukaemogenesis.

Applicant respectfully traverses this rejection.

Under 35 U.S.C. §103, the factual inquiry into obviousness requires a determination of: (1) the scope and content of the prior art; (2) the differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) secondary considerations. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966). When considering the differences between the claimed subject matter and the prior art, MPEP 2141.02 instructs that a prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

In this regard, Applicant respectfully disagrees with the Examiner's conclusion that it would have been obvious to combine the teachings of the cited references with the motivation to

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study the effect of c6.1A gene expression loss to discover its affect, if any, on T-cell leukaemogenesis. Fisch teaches that the association of c6.1A with pro-lymphocytic leukemia is due to a chromosomal translocation occurring in two different introns of the c6.1A gene. Fisch demonstrates that the result of the translocation is a fusion transcript between c6.1A and TCR C α , which is abundantly expressed only in leukemic cells. See column 2 at page 3272. Most pointedly, however, Fisch specifically indicates that the results therein "strongly suggest that the c6.1A-C α chimeric transcript as such, although expressed at high levels, cannot be relevant for leukaemogenesis in T-PLL" [emphasis added]. See paragraph 1, column 1, at page 3274. Thus, contrary to the Examiner's assertion, one skilled in the art would NOT be motivated to study the effect of c6.1A gene expression loss to discover its role in T-cell leukaemogenesis, because Fisch expressly assert no role for this protein in T-cell leukaemogenesis.

The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "'[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *KSR*, 550 U.S. at __, 82 USPQ2d at 1396. See also MPEP 2141. In the present case, there is simply no rationale for combining the cited references in the manner suggested by the Examiner. Therefore, it is respectfully requested that this rejection under 35 U.S.C. 103(a) be reconsidered and withdrawn.

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IV. Conclusion

Applicant believes that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claim is earnestly solicited.

Respectfully submitted,



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